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NSF/ANSI Standard for Food Equipment —

Manual food and beverage dispensing equipment

6 Performance

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6.4 Dispensing equipment without temperature controlled storage of potentially hazardous food or beverages

The requirements in 6.4 apply only to dispensing equipment that is equipped to:

- a) accommodate specially-designed, single-use, collapsible containers of aseptically processed and packaged potentially hazardous food or beverage in a homogeneous, liquid form; and
- b) apply a mechanical barrier or aseptic valve in combination with a specially designed package to maintain the commercial sterility of the food or beverage in the container while it is held without temperature control within the dispensing equipment; and
- c) mechanically open the aseptic packaging in a sanitary manner while the product container is inside the dispensing equipment; and
- d) maintain the function of the mechanical barrier or aseptic valve as part of specially designed package by means of an automated control mechanism that is factory-adjusted to assure proper closure between product dispenses and under all conditions of equipment and material tolerances; and
- e) prevent dispensing of product if the mechanical barrier or related automated control mechanism does not function as intended.

6.4.1 Mechanical barrier effectiveness

Dispensing equipment shall employ a mechanical barrier that, in conjunction with the sanitary design of the equipment, is capable of maintaining the commercial sterility of the potentially hazardous food or beverage product under conditions without temperature-controlled storage in the dispensing equipment. The mechanical barrier shall be effective in preventing the entry of microorganisms while the product container is being opened and during periods of product holding and dispensing.

6.4.1.1 Test methods

Microbiological methods for stock culture preparation, and enumeration/analysis of samples, shall be performed as specified in annex B. Barrier tests shall be conducted at an ambient temperature of $86 \,^{\circ}\text{F} \pm 4 \,^{\circ}\text{F}$ ($28 \,^{\circ}\text{C} \pm 2 \,^{\circ}\text{C}$).

6.4.1.1.1 Static barrier test

The product container shall be installed according to the manufacturer's directions including closing of the mechanical barrier, but without removing the container's original hermetic seal. A small volume (~0.1 mL) of product, downstream of the mechanical barrier (non-sterile area), shall be aseptically replaced with a mixed inoculation culture using sterile syringes. The equipment shall be left idle for 48 h to allow bacterial attachment and growth. Five 1 mL samples shall be aseptically retrieved, using a sterile syringe or other sterile method of retrieval, from the sterile section of tubing immediately upstream of the mechanical barrier (sterile area) and shall be divided into two 0.5 ml aliquots and plated on Tryptic Soy Agar (TSA). Each of the 0.5 mL test samples shall be analyzed as specified in annex B. If growth is expressed on the TSA plates from the sterile area, confirmation of the organism identity will be performed via appropriate test methods. The product closure shall be opened manually, and the inoculated non-sterile area shall be swabbed. Swabs from the non-sterile area shall be analyzed as specified in annex B.

6.4.1.1.2 Dynamic barrier test

The product container shall be installed according to the manufacturer's directions including closing of the mechanical barrier, but without removing the container's original hermetic seal, A small volume (~0.1 mL) of product, downstream of the mechanical barrier (non-sterile area), shall be aseptically replaced with a mixed inoculation culture using sterile syringes. The equipment shall be left idle for 24 h to allow bacterial attachment and growth. The container's hermetic seal shall be removed, and the equipment shall be operated to dispense a representative volume of product at a rate not to exceed one dispense (mechanical barrier actuation) per hour until the product container is almost, but not completely, empty. The equipment shall be left idle for 48 h after the last actuation. Five 1 mL samples shall be aseptically retrieved, using a sterile syringe or other sterile method of retrieval, from the sterile section of tubing immediately upstream of the mechanical barrier (sterile area) and shall be divided into two 0.5 ml aliquots and plated on Tryptic Soy Agar (TSA). Each of the 0.5 mL test samples shall be analyzed as specified in annex B. If growth is expressed on the TSA plates from the sterile area, confirmation of the organism identity will be performed via appropriate test methods. The inoculated non-sterile area shall be swabbed. Swabs from the non-sterile area shall be analyzed as specified in annex B. This entire procedure shall be repeated at least once with a new product container and as necessary to obtain at least 100 actuations of the mechanical barrier.

6.4.1.2 Acceptance criteria

For each sample in 6.4.1.1.1 and 6.4.1.1.2, 1 mL samples shall be negative for *Listeria innocua* and *Brevundimonas diminuta*, and swab samples shall be positive for *L. innocua* and *B. diminuta*.

6.4.2 Dispensing lockout verification – Duration of storage

Dispensing equipment shall be designed to prevent dispensing of product that has been held in the equipment under non-temperature-controlled conditions beyond the time limit prescribed by the equipment manufacturer. A dispensing lockout that cannot be manually overridden shall be activated when the maximum time limit specified by the manufacturer is reached. The lockout function shall operate on an internal clock that is not affected by interruptions in electrical power. The maximum potentially hazardous food storage time specified by the manufacturer shall be no more than seven days.

6.4.2.1 Test method

The dispenser shall be provided with a fresh, new container of product to be dispensed, and operated in accordance with the manufacturer's instructions. The dispenser shall be operated to dispense three portions at the smallest portion setting. Time and date shall be noted, and the unit shall be allowed to remain in service for the maximum potentially hazardous food storage time specified by the manufacturer. After the elapsed time, an attempt shall be made to dispense product.

6.4.2.2 Acceptance criteria

The dispenser shall not dispense product.

6.4.3 Disposal of remaining product during change-container sequence

Dispensing equipment shall be designed to prevent the reuse of a container of potentially hazardous food or beverage that has already been held in the dispensing equipment. To prevent the reuse of a partially emptied container, the change-container sequence shall automatically empty and discard product from the container prior to its removal from the dispensing equipment.

6.4.3.1 Test method

The dispenser shall be provided with a fresh, new container of product to be dispensed, and operated in accordance with the manufacturer's instructions. The dispenser shall be operated to dispense three portions at the smallest portion setting. The "change container" sequence shall be activated and the product container removed in accordance with the manufacturer's operating instructions.

6.4.3.2 Acceptance criteria

The removed container shall contain no more than 300 mL of the original product volume.

6.4.4 Dispensing lockout verification – Power failure/malfunction during dispensing

Dispensing equipment shall be equipped with a dispensing lockout that is activated if the mechanical barrier mechanism fails to function in a manner that prevents the entry of microorganisms during an interruption of electrical power to the equipment or other malfunction. If an interruption of power or other malfunction occurs while product is being dispensed and the mechanical barrier does not fully close automatically, there shall be a visual indicator that a change of product container is required, and dispensing shall be locked out until a new potentially hazardous food container is installed.

6.4.4.1 Test method

The dispenser shall be provided with a fresh, new container of product to be dispensed, and operated in accordance with the manufacturer's instructions. The unit shall be operated to dispense three portions at the smallest portion setting. During the last dispensing operation, the power to the machine shall be turned off while the mechanical barrier is open. The mechanical barrier shall be observed for proper functioning/closure. After a minimum of 15 s, the power shall be restored to the unit. An attempt shall be made to dispense product.

6.4.4.2 Acceptance criteria

The mechanical barrier shall close automatically when the power is interrupted or, upon restoration of power, a visual indicator shall be activated and the dispenser shall not dispense product until the existing container is removed and a new product container is installed.